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Analysis of events related to packaging of health products processed by SPD during storage

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Abstract: **Objective:** identify the main types of materials involved in related events damaged packaging inside the surgical center arsenal. **Method:** application project for monitoring the waste material at the time of storage, held in large hospital, philanthropic, in Sao Paulo, in the period from September to December 2016. After the identification of weaknesses in the material packaging was carried out one process improvement intervention. **Results:** Through the monitoring of materials, It identified those with the events and thus proposed intervention with guidance d WEC nursing technicians as to the best type of packaging for certain health products. **Conclusion:** Although we have not achieved a score of 100% in relation to the events related to packaging, it was possible to reduce considerably, at least 50% the number of contamination during storage

Keywords: Storage products;sterilization;product packaging

1. Introduction

The RDC 15, 2012 classifies Sterilization Process Department (SPD) into two classes I and II, and the class I SPD that performs processing products for health non-critical, semi-critical and critical conformational not complex and amenable to processing, and the SPD class II performs, in addition to those previously mentioned, the processing of complex materials, if those health products that have a lumen less than five millimeters or blind bottom, internal spaces inaccessible to direct friction , recesses or valves [1].

The RDC No. 50, 2002 and RDC No. 15, 2012 highlights the uncrossed flow (cleaned area separated from the clean area) within the SPD, among other key recommendations and actions on the facilities and physical structure in which SPD is to carry out its work [2].

SPD must own the following environments: ward reception and cleaning (dirty sector); preparation and sterilization room (clean sector); chemical disinfection room, when applicable (clean sector); area of monitoring of the sterilization process (clean sector); and storage and distribution room for sterilized materials (clean sector). And each of them has a temperature monitoring, pressure and relative humidity so that product quality is guaranteed [1,3-4].

As for storage, it is that health products sterilized should be placed in a clean, dry place under protection from direct sunlight and subject to minimal handling, stored in locations separately from health products unsterilized [1,3-4].Although RDC nº15 does not bring temperature and humidity values, the literature offers some recommendations on the storage conditions of sterile materials, such as temperature controlled between 18 and 24°C, relative humidity of 40% to 60% (there are variations in these measures according to different studies); air renewal with at least 15 exchanges

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per hour; restricted access; to be distant from water sources, from open windows and doors, and from exposed pipes; products should be stored in organized spaces, identified shelves for easier viewing, identification and access; the building materials of the shelves must be washable, made of stainless steel, plastic or aluminum; there should be periodic cleaning routine of the storage location; storing the materials after cooling to avoid condensation when sterilized at high temperature; and the area must be sized for the volume of items received, in addition to having the least possible manipulation[3,4].

All sterile materials should be inspected before use and it is important to check their expiration date, package integrity, presence of stains or moisture in the package and chemical exposure indicator (zebra tape) to ensure the quality of the material being delivered for use [3,4].

The packaging is intended to ensure the sterility of the product until the moment of use and must be carefully selected taking into consideration the type of material to be packed, size, weight and regular or irregular conformation and presence of sharp points. The material can be packed in one or more layers depending on use, storage and transport.

It is considered primary packaging that comes in direct contact with the product to be sterilized; This system should be effective as protective material regard to the entry of microorganisms following sterilization, maintaining a sterile product to the use of [5,6].

During the packaging process you can choose to do more than one layer, thus creating the secondary packaging, creating a package within the package, protecting its content and facilitating aseptic opening at the time of use[5,6].

There may also be the use of a third pack, called a cover bag, providing extra protection during storage and transport and being added after sterilization of the product. This third layer can be formed of adherent plastic film, plastic container or plastic bag.

The containers must have a notification record in ANVISA, be appropriate to the sterilization method allowing the entry and removal of the sterilizing agent and effective barriers to the passage of microorganisms, liquids and particles. They must be resistant to tears, holes and abrasions, promote hermetic sealing, have dimensions that suit various product sizes and contain specific impregnated chemical exposure indicators for each method of sterilization.

The main types of packaging currently found are: cotton tissue, crepe paper, SMS blanket (SMS nonwoven tissue), Tyvek®, container hard[3-6]. After sterilization, the product should be stored in its own place and handled as little as possible, thus preventing the packaging from being damaged before use.

Therefore, this study is objective is identifying the main types of materials involved in related events damaged packaging inside the storage at the surgical area.

2.Method

This study is based on an application design. The application project aims to produce innovations or support the transformation of practices, processes or products in health and in the context of the Brazilian health system[7].

The study was conducted in a private SPD hospital of Sao Paulo, Brazil in the period from September to December 2016.

The SPD is classified as class II by performing complex compliance materials processing. It has 1.2mil m² and counts on the areas of reception and cleaning, preparation of materials, steam sterilization and sterilization at low temperature, distribution area and arsenal. The SPD counts on equipment to aid in the processing of materials, totaling two ultrasonic washers and two three chamber thermodynesters, a car washer, a dryer of trachea, four steam autoclaves and three autoclaves at low temperature.

The material follows the flow recommended by RDC No. 15, 2012, being received in the reception and cleaning area and is subjected to manual pre-cleaning followed by automated washing in the thermodesinfector or ultrasonic

depending on its complexity. It goes to the preparation area, where it is pre-inspected and placed for preparation. At this time the material is reviewed to ensure that there is no dirt, packaged and identified, and is transferred to the sterilization area, whether it is steam or low temperature.

The packaging used in the service are: SMS blanket, surgical paper, Tyvek® and rigid container. Most of the material is currently packaged in single-pack SMS packages - instrument boxes - or surgical grade in double packaging - usually bulk materials. The Tyvek® is only used as simple packaging and containers have a filter for penetration of the sterilizing agent and the side seals.

After packing, the material is arranged in the autoclave rack so that the sterilizing agent can come in contact with its entire surface. After sterilization, the material is distributed to its use of industry - most of them to the armory of the operating room, since the increased flow of materials is from there, this material is transported in itself and closed car.

The arsenal is strategically located within the surgical center, connected to the SPD by a restricted access corridor. Materials are stored in properly identified iron cabinets and drawers.

The temperature and relative humidity are controlled between 18 and 24°C and 40 to 60%, respectively. There is a routine to check the validity and cleaning dates of the cabinets once a week on weekends, and also to check the integrity of the packaging, which, if damaged, is sent back to the SPD for reprocessing.

There are many factors that can interfere in the sterility of health products, such as cleaning, use of adequate packaging, sealing, the sterilization itself and its storage, especially in the last item, the shelf life of the product.

Although each institution has its shelf-life based on its sterilization and storage conditions, there is a strong discussion today that, more important than the shelf-life is to analyze the packaging conditions before use of the material.

Thus, the first step of this project was the construction of decision-making matrix for problem identification with name, term viability and feasibility. In this study the most important problem was the number of sterile materials packaging integrity compromised during storage.

This check of the integrity of the packaging should become routine and not a task to be performed only on weekends. It is expected that this rigorous inspection will be carried out with each manipulation of the material, thus ensuring that no contaminated material is sent to the operating room.

The second step in building this is to identify the actors involved in the process: hospital infection control commission nurse, SPD nurse coordinator, SPD nurses, SPD and CC nursing technicians.

Next, the descriptor is to verify and measure the problem to be faced, pointing their negative charges and facilitating the construction and monitoring of interventions[7].

During the month of October 2016 the night nurse identified some damaged packaging at the time it was reviewing the operating room before the start of surgery the first time of the day. Posted up in just one night, five broken packages, including two in SMS blanket and three paper Tyvek®. After this finding, she reviewed some arsenal cabinets to make sure that nothing else was damaged, but found another 18 packaging paper Tyvek® with compromised integrity.

Facing this event, the descriptor of this project was defined as high number of materials with damaged packaging. With this, the explanatory tree of the problem is started to direct the construction of the action plan and initiated the intervention to solve the identified problem.

During the first week of the intervention, the employee who was responsible for the storage in the surgical area should inspect all's the materials sent to the surgical area to ensure the integrity of all packaging and if he found any damaged packaging, and return to SPD for reprocessing, he should note the material that was identified in a spreadsheet constructed by the resident nurse of the SPD for this purpose. (Table 1)

The fill should contain the date and only the quantity of materials with identified damaged packaging, according to its packaging, it was recommended that they describe the type of material.

All damaged, punctured or stained containers were considered as damaged containers and, in the case of containers, the lack of a seal or filter.

Date	Surgical grade	SMS Blanket	Tyvek ®	Container

Table 1. Simplified template provided to SPD employees for registration of damaged packaging.

In the second week, after identifying the major types of packaging that were suffering damage to their integrity, the resident nurse, unit nurses, and nurse coordinator discussed the possibility of changes in the preparation of materials in accordance with the conditions and needs of the SPD.

The third week was held the orientation of the SPD nursing technicians regarding the change of packaging applied to health products.

In the fourth week they were implemented new packaging and the re-evaluation of the effectiveness through visual inspection and registration spreadsheet.

3.Results

They identified a total of 56 damaged packaging, 26 surgical grade, 17 SMS blanket, 12 in Tyvek® and 1 container. Among the materials involved in the events leading we can cite urology tray made in the packed Tyvek® (5 units) and optical (4 units) and angular materials in surgical grade paper (20 units).

Thus, during the discussion with the nurse coordinator of the unit and the other nurses aligned area, as well as surgical - grade packaging, packaging paper Tyvek® also would double and considering the size of the material and weight, the trays of urology and optics were packed in SMS only. For materials packed in surgical grade paper, reinforced only need to use edge protectors at the time of preparation, since they were not always being used and materials SMS blanket was also reinforced the need for the cover bag after the sterilization of the material, providing a protective layer in the package.

Later the orientation of the SPD nursing technicians was done through individual conversations and group during the third week of October, with 100% participation and for future reference, were also made available information about the change in preparation benches of materials.

After the intervention we can note that there were no events related to containers, a decrease of 82% of events with the paper packaging Tyvek®, 58% with SMS blanket and 50% of surgical grade (Figure 1).

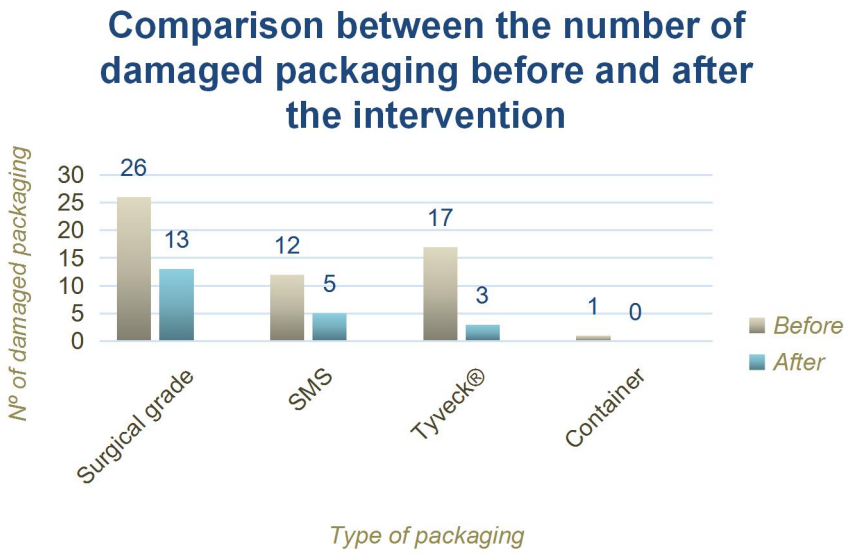

Figure 1. Comparison between the number of damaged packaging before and after the intervention

4.Discussion

The results of this work show a significant reduction in the damage to the packages of sterile material. Changing the work routine through an application project built by a resident nurse exemplifies that improvement in processes can reduce costs and expenses in preparing materials for loss of packaging, and indirectly help reduce possible surgical site infections.

Hospital infections can be defined as infections that occur in patients during hospitalization, with diagnosis confirmed by clinical and laboratory tests. Currently, the control and prevention of Health Care Related Infections (IRAS) has been a challenge for hospital institutions, being a complex and highly responsible practice, requiring scientific knowledge and evidence. According to the European Center for Disease Prevention and Control on average 20 to 30% of HAI can be prevented by control programs and intensive care[8].

Surgical Site Infection (SSI) is one of the main infections related to health care in Brazil, occupying the third position among all infections in health services, comprising 14% to 16% of those found in hospitalized patients. A national study conducted by the Ministry of Health in 1999 found an ISC rate of 11% of all surgical procedures analyzed. This rate is more relevant because of factors related to population served and procedures performed in health services[8].

SSI is a relevant complication, since it contributes to the increase in mortality and morbidity of post-surgical patients causing physical and emotional losses, such as work and social withdrawal, and considerably increase costs with treatment, in a longer hospital stay[9-10].

It is known that there are numerous factors that may be related to an SSI from intrinsic, such as the patient's clinical conditions and presence of co morbidities, by extrinsic factors such as extended preoperative hospitalization time, duration of surgery, skin preparation, environmental conditions in the operating room, sterile materials, number of people inside the room, among others[9-10].

It stands out here the sterile material. All the process of the medical device must be monitored and controlled in order to ensure their quality until the time of use. Ensuring the integrity of the surgical material until its use is a surgical site infection prevention strategy.

No similar studies available for comparison of the data found, but it is believed that the change of practice contributes to the security of the material sterility process and consequently to patient safety.

It can be a practice to be disseminated to other institutions to ensure a longer term for packaging integrity and less reprocessing of materials.

Further research should be conducted to evaluate the loss of packaging or the quantitative reprocessing of materials for loss of sterility, helping to reduce the costs of the hospital unit.

5.Conclusion

Although we achieved a score of 100% in relation to the packaging - related events, a significant reduction was observed in at least 50% the number of contamination during storage.

It is believed that other factors may be involved in events beyond the choice of packaging, such as packaging material and the number of manipulations that the material undergoes during storage, but more studies are needed on the subject so that we can ensure that the packaging is intact at the time of use.

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